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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/768,917	01/24/2001	Alain P. Vicari	SF0896K	5028

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SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER	
WEHBE, ANNE MARIE SABRINA	
ART UNIT	**PAPER NUMBER**
1633	

DATE MAILED: 04/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/768,917	VICARI ET AL.	
	Examiner	Art Unit	
	Anne Marie S. Wehbe	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-24,27,29,31,33,35,36 and 69* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-24, 27, 29, 31, 33, 35-36, and 69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment and arguments filed on 1/26/06 have been entered. Claims 21-24, 27, 29, 31, 33, 35-36, and 69 are currently pending and under examination in instant application. An action on the merits follows.

Those sections of Title 35, US code, not included in this action can be found in a previous office action.

Claim Rejections - 35 USC § 112

The rejection of claims 21-24, 27, 29, 31, 33, 35-36, and 69 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn in view of applicant's amendments to claims 21 and 36.

The rejection of claims 21-24, 27, 29, 31, 33, 35-36, and 69 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is withdrawn in view of applicant's amendments to claim 21.

The following new grounds of rejection apply to the claims, therefore this action is non-final.

Claim Rejections - 35 USC § 103

Claims 21-24, 27, 29, 31, 33, 35-36, and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 974 357 A1 (7/16/98), hereafter referred to as Caux et al., in view of WO 98/14573 (4/9/98), hereafter referred to as Luster et al., and Dieu-Nosjean et al. (1999) J. Leuk. Biol. Vol. 66, 252-262. Please note that this grounds of rejection was previously applied to the claims and was withdrawn in the office action mailed on 7/28/05 in view of applicant's amendment to claim 21 which now recites the sequential administration of a protein chemokine and a nucleic acid encoding an antigen, wherein said chemokine is MCP-4. The previous office action indicated that the scope of the claims as amended is now commensurate in scope with the evidence of "unexpected results" provided by the Declaration under 37 CFR 1.132 by Dr. Vicari. However, upon further consideration, it has been appreciated that the term "sequentially", while indicating that protein and nucleic acid are not administered together, does not place any limit on the order of administration of the protein and nucleic. In other words, the claims as written read both on the administration of the protein chemokine followed by the nucleic acid and vice versa. As such, the scope of the claims as written is not commensurate in scope with the declaratory evidence of "unexpected results" as set forth in the Declaration by Dr. Vicari under 37 CFR 1.132, of record. Therefore, the previous grounds of rejection based on the teachings of Caux et al., Luster et al. and Dieu-Nosjean et al. have been reapplied as set forth below.

As noted in previous office actions, while the EP 0 974 357 A1 document no longer qualifies as prior art under 102(a) regarding subject matter relating to MCP-4, this document

does qualify as prior art in regards to the teachings contained therein relating to other chemokines such as MIP-3α.

Caux et al. teaches methods of using chemokines in combination with antigens for directing the migration of antigen presenting cells, including dendritic cells, to lymphoid organs in vivo in order to increase immune responses (Caux et al., columns 4-7, and 18-19). In particular, Caux et al. teaches the delivery of chemokines as a protein in combination with a nucleic acid encoding a viral or tumor antigen (Caux et al., columns 6-7, and columns 18-19, claims 11-14). Caux et al. defines combined administration as meaning " the chemokine and antigen are administered to the subject either (a) simultaneously in time, or (b) at different times during the course of the common treatment schedule" (Caux et al., column 7, lines 10-14). Caux et al. further teaches the administration of non-methylated CpG as an "activating agent", the co-administration of GM-CSF and IL4, and the administration of the chemokine intradermally or intramuscularly (Caux et al., column 19, claims 17-20). Regarding the nature of chemokines useful for treating disease and inducing immune responses, Caux et al. teaches the use of chemokines, including MIP-3α, MIP-1α, and RANTES, which are capable of attracting and/or activating antigen presenting cells (Caux et al., columns 1-4).

While Caux et al. cannot be used as prior art for teaching the chemokine MCP-4, Luster et al. supplements Caux et al. by teaching the administration of human MCP-4 in the form of a protein in order to stimulate immune responses in a mammal (Luster et al., pages 4-5, particularly page 5, lines 9-12). Luster et al. also teaches the construction and use of both bacterial and eukaryotic vectors encoding MCP-4 to express MCP-4 *in vivo*. (Luster et al., page 50). Luster et al. further teaches the MCP-4 is chemotactic for antigen presenting cells such as

monocytes (Luster et al., pages 34-35). Dieu-Nosjean et al. further supplements Luster et al. by teaching that MCP-4 is capable of causing the activation and migration of dendritic cells (Dieu-Nosjean et al., page 255, Table 2). Thus, based on the known properties of MCP-4 in activating and attracting dendritic cells, and the teachings of Luster et al. that MCP-4 can be use to induce immune responses *in vivo* for the treatment of disease, it would have been *prima facie* obvious to the skilled artisan to use MCP-4 as the chemokine in the methods of inducing immune responses comprising administering a nucleic acid encoding an antigen and a protein chemokine taught by Caux et al. Furthermore, based on the detailed teachings of Luster et al. for both protein and nucleic acid forms of human MCP-4, the skilled artisan would have had a reasonable expectation of success in co-administering an antigen and human MCP-4 in order to induce an immune response in a mammal.

Finally, as noted in previous office actions, the declaration by Dr. Vicari under 37 CFR 1.132 demonstrates that the injection of hMCP-4 protein **prior to** the administration of nucleic acid encoding an antigen increases antigen specific IgG antibody generation, whereas prior injection of hMIP-3α does not. As discussed above, the claims as written, while reciting sequential administration, are not limited to a sequence of administration wherein the MCP-4 protein is administered before the administration of the nucleic acid encoding the antigen. The previous office quoted the MPEP in section 716.02(d) which states that in the consideration of evidence of unexpected results, "Whether the unexpected results are the result of unexpectedly improved results or a property not taught by the prior art, the 'objective evidence of nonobviousness must be commensurate in scope with the claims which the evidence is offered to support.'", citing *In re Clemens*, 622 F.2d 1029, 1036, 206 USPQ 289, 296 (CCPA 1980) (see

also *In re Peterson*, 315 F. 3e 1325, 1329-31, 65 USPQ2d 1379, 1382-85 (Fed. Cir. 2003), and *In re Grasselli* 713 F.2d 731, 741, 218 USPQ 769, 777 (Fed. Cir. 1983)). In the instant case, the evidence provided to demonstrate "unexpected results" and thus non-obviousness is not commensurate in scope with the claims as written.

It is suggested that claim 21 be amended to indicate that the protein chemokine is administered prior to the nucleic acid encoding the antigen in order to overcome this grounds of rejection.

No claims are allowed.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. If the examiner is not available, the examiner's supervisor, Dave Nguyen, can be reached at (571) 272-0731. For all official communications, **the new technology center fax number is (571) 273-8300**. Please note that all official communications and responses sent by fax must be directed to the technology center fax number. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737. For any inquiry of a general nature, please call (571) 272-0547.

The applicant can also consult the USPTO's Patent Application Information Retrieval system (PAIR) on the internet for patent application status and history information, and for electronic images of applications. For questions or problems related to PAIR, please call the USPTO Patent Electronic Business Center (Patent EBC) toll free at 1-866-217-9197. Representatives are available daily from 6am to midnight (EST). When calling please have your

application serial number or patent number available. For all other customer support, please call the USPTO call center (UCC) at 1-800-786-9199.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER